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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	RDID 02081 US	4047
7590 12/21/2007 Brent A. Harris Roche Diagnostics Corporation Bldg. D 9115 Hague Road Indianapolis, IN 46250-0457			EXAMINER HYUN, PAUL SANG HWA	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/628,042	Applicant(s) MARQUANT ET AL.	
	Examiner Paul S. Hyun	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,11-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,11-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/07, 10/4/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

REMARKS

Claims 1-28 were previously pending. By the present amendment, Applicants cancelled claims 5, 9, 10 and 23, and amended claims 1, 6, 7, 11, 22 and 24. In summary, claims 1-4, 6-8, 11-22 and 24-28 are pending for examination on the merits.

The amended Abstract filed by Applicants has been acknowledged. Consequently, the objection has been withdrawn.

The amendment to the title has been acknowledged. Consequently, the objection has been withdrawn.

The objection to the Drawings has been withdrawn in light of cancellation of claim 9.

The claim objections cited in the previous Office action have been withdrawn in light of the amendments.

The claim rejections under 35 U.S.C. section 112 cite in the previous Office action have been withdrawn in light of the amendments/clarification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-4, 6, 15-17, 19-22, 24 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. (US 2002/0079219 A1) in view of Ekström et al. (US 5,376,252).

Zhao et al. disclose a microfluidic device for conducting electrochemical analysis of liquid samples (see Fig. 3C and Abstract). The device comprises a microfluidic channel 99 formed between adhered layers 92 and 94. The microfluidic channel is lined with a layer of electrode 96 (see [0090]) wherein the electrode can be made from conventional electrode materials such as gold (see [0071]). The electrode comprises a connecting section that extends beyond the layers that define the microfluidic channel (see Fig. 2). The microfluidic channel leads to a measuring site where electrochemical analysis is conducted (see Fig. 22A and 22B and [0148]). In addition to the electrode, the measuring site can comprise a reference electrode and a counter electrode. The device can also be used to conduct hybridization assays with reagents immobilized at specific sites of the device (see [0103]). The device disclosed by Zhao et al. differs from the claimed device in that it does not comprise multi-tiered layers. Zhao et al. also do not disclose a layer made from insulating foil material or a transparent window for observing the sample fluid.

Ekström et al. disclose a microfluidic device for processing fluid samples (i.e. separation, detection) (see Fig. 7A). The device comprises vertically alternating layers 2 and 3 such that a plurality of channels 4 defined by recesses/gaps in layer 3 are aligned on top of one another. Ekström et al. disclose that the stacked configuration enables the formation of multi-storied structures and complex channel geometries for conducting

reactions and analyses (see lines 25-35, col. 8). In light of the disclosure of Ekström et al., it would have been obvious to one of ordinary skill in the art to stack the layers of the microfluidic device disclosed by Zhao et al. to form multi-storied microfluidic channel networks. The multi-storied configuration would enable complex reactions and analyses.

With respect to claim 4, Ekström et al. disclose that base layer 2 may be made from electrically insulating foil (see lines 60-65, col. 3). In light of the disclosure of Ekström et al., it would have been obvious to one of ordinary skill in the art to form the base layer of the Zhao et al. device from an insulating foil since the layer comprises electrodes.

With respects to claim 19, it should be noted that the claimed control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation "for checking the filling... control site" does not further limit the structure of the control site.

With respect to claim 20, Ekström et al. disclose that the channels of the device may be provided with transparent windows for observing the fluid sample within the channel (see lines 30-60, col. 9). In light of the disclosure of Ekström et al., it would have been obvious to provide the Zhao et al. device with an optically transparent window to provide the device with a means for observing the sample flow.

Claims **7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Akridge et al. (US 5,141,614).

Neither Zhao et al. nor Ekström et al. disclose the use of the claimed electrode/counter electrode combination.

Akridge et al. disclose the use of gold working electrode and Ag-AgCl counter electrode combination for detecting dissolved oxygen (see lines 5-10, col. 10).

In light of the disclosure of Akridge et al., it would have been obvious to one of ordinary skill in the art to provide the modified Zhao et al. device with a gold working electrode and Ag-AgCl counter electrode combination so that it can be used to detect dissolved oxygen.

Claims **11-13, 25, 27 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Oloman et al. (US 4,118,305).

Neither Zhao et al. nor Ekström et al. disclose a hydrophilic insulating material comprising perforations.

Oloman et al. disclose an electrochemical device for conducting reactions wherein the device comprises an electrode, a counter electrode and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes.

In light of the disclosure of Oloman et al., it would have been obvious to one of ordinary skill in the art to provide a hydrophilic, porous insulating layer around the

working and the counter electrodes of the modified Zhao et al. device so that flow of liquid to the electrodes is permitted while providing electrical insulation.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Stapleton et al. (US 5,922,604).

Neither Zhao et al. nor Ekström et al. disclose that the reagents are dry.

Stapleton disclose a microfluidic device comprising dry reagents immobilized to the surface of the microfluidic channels (see lines 40-50, col. 11).

In light of the disclosure of Stapleton et al., it would have been obvious to one of ordinary skill in the art to provide dry reagents to the modified device disclosed by Zhao et al. and Ekström et al. to extend the shelf life of the reagents.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al. in view of Ekström et al. as applied to claims 1-4, 6, 15-17, 19-22, 24 and 26, and further in view of Weigl et al. (US 2001/0027745 A1).

Neither Zhao et al. nor Ekström et al. disclose a vent.

Weigl et al. disclose a microfluidic device comprising vents (see [0100]). The vents allow directional flow of fluids.

In light of the disclosure of Weigl et al., it would have been obvious to one of ordinary skill in the art to provide vents to the modified Zhao et al. device so that fluid flow can be controlled.

Response to Arguments

Applicant's arguments with respect to the art rejections have been fully considered but they are not persuasive. Applicants argue that it is not feasible to multi-layer the Zhao et al. device. This argument is not persuasive because Ekström et al. demonstrate that it is possible to form multi-layered microfluidic devices that comprise electrodes. Figures 1, 2, 5 and 10 Ekström et al. show embodiments of the invention comprising electrodes in the substrate layer, and Figure 7A shows that layers of substrates can be assembled to form a multi-tiered device. Based on the disclosure, there is motivation for stacking the layers of the Zhao et al. device to form multi-layered device wherein each unit comprises a substrate 18, electrodes 28 and a cover 20 as shown in Fig. 2 of Zhao et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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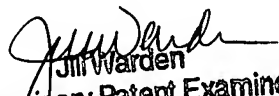
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
12/17/07


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